# Audit

Rebecca Dahl, Ph.D.
Director, Human Subjects Protection Program

# Audit

## Federal Regulations

"An IRB shall conduct continuing review of research covered by this policy [regulation] at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research 45 CFR 46.109(e)"…additionally, the IRB is also required by 45 CFR 46.111(a)(6) and 21 CFR 56.111(a)(6) to ensure that when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."

Bankert & Amdur , 2006

# Audit

- Policies and Procedures - Written guidelines on how reports are to be handled
  - Ensures consistency and adherence
  - Once written, policies and procedures must be made available to the research community

Bankert & Amdur , 2006

# Audit

## Ongoing Activities

- Review FDA and OHRP letters to other institutions
  - Warning letters are available on the FDA's Web page
    - Provides guidance
    - Demonstrates deficiencies that are of concern

Amdur & Bankert, 2002

# Audit

How do problems get reported?

- Protocol deviations
- Amendments
- Safety monitoring reports
- Serious adverse event reports
- Complaints
- Interim findings
- Other reports

Amdur & Bankert, 2002

# Audit

## What to do to prepare for an audit

- Notify
  - Institutional Official
  - Department Head
  - Investigator
- Review internal documents (protocol, consent forms, other related material)
- Prepare standardized form

Amdur & Bankert, 2002

# Audit

## What to do to prepare for an audit

- Focus of the review - research records
  - Source documents (medical records)
  - Case Report Forms
  - Signed consent forms
  - IRB approvals
  - Other (e.g., communication and correspondence)

Amdur & Bankert, 2002

# Audit

## What to do to prepare for an audit

- Ask for a workspace (away from the workflow area)
  - Private office or conference room (lockable and available for the full inspection time)
  - Off-site area (needs to be reasonably close)
  - Table, chairs for meeting with the investigator and study staff
  - Access to a copier and telephone

Amdur & Bankert, 2002

# Audit

## Pre-audit

- Orientation
  - Give a brief overview about the audit
  - If there are unique issues regarding the study, these need to be included in the orientation

Amdur & Bankert, 2002

# Audit

## During the Audit

- “Mini Update”
  - Ask for additional needed items
  - Answer questions
  - Set the agenda for the next phase of the audit (if needed)

Amdur & Bankert, 2002

# Audit

## During the Audit

- "Mini Update" (cont.)
  - Prepare notes, reports, or briefings of the day's activities
  - Discuss preliminary concerns and assist the Investigator with planning for any corrective actions that appear to be forthcoming

Amdur & Bankert, 2002

# Audit

## During the Audit

- Study Files - (mark critical letters and reports)
  - Include files that meet certain requirements
- Review source documents
  - Portions may be copied (for later analysis)

Amdur & Bankert, 2002

# Audit

## During the audit

- Interviews
  - Members of the research team
  - Study subjects
  - Other personnel (if needed)
    - Keep a list of who was interviewed
    - Keep notes of what was said during the interview

Amdur & Bankert, 2002

# Audit

## Exit Interview

- Gather appropriate members of the team, Principal Investigator, institutional officials
  - May be given deficiencies
  - May be an oral summary
  - May be in writing

Amdur & Bankert, 2002

# Audit

## Exit Interview

- Review draft of the audit report with key personnel
  - Request clarification if needed
  - Correct any errors
  - Include concerns that were corrected during the audit

Amdur & Bankert, 2002

# Audit

## Exit Interview

- May include positive and negative comments
- Discuss possible correction plan
- Discuss when a written report will be available

Amdur & Bankert, 2002

# Audit

## Post audit

- Begin final version of audit report
  - Respond in writing with items that need correction on the audit form
  - Include detailed history of the audit, findings, and recommendations (cite Policies and Procedures and federal regulations)
  - Submit audit report to Institutional officials, attorney's office, Institutional Review Board

Amdur & Bankert, 2002

# Audit

## Post audit

If evidence of serious or continuing noncompliance is found, a report must be made to the Institutional Official and the Office for Human Research Protections (45 CFR 46.103(b)(5)

- If FDA regulated product is involved, the FDA must be notified (21 CFR 56.108(b)(2)

Amdur & Bankert, 2002

# Audit

## Post-audit

- Appropriate follow-up must be included to ensure that deficiencies are corrected in a timely manner
  - Report from the Investigator (corrective actions implemented by the Investigator)
  - May require additional auditing or monitoring
  - May additional requirements of the Investigator

Amdur & Bankert, 2002

# Audit

## Summary

"A research audit program can be an integral component of an institution's efforts to enhance the ethical quality of its research. It also ensures that compliance with applicable federal and state regulations is maintained."

Bankert & Amdur, 2006, p.56